

## [510(k)] SUMMARY OF SAFETY AND EFFECTIVENESS

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This submission notifies the FDA of a our intention to replace the HP M1403A Telemetry Monitoring System, K894277 with a new system. The new system will be marketed as the HP M2600A OmniCare Telemetry System. The new system is very similar to the replaced system except for several added features. The design was leveraged off of development work (RF, ECG, and SpO<sub>2</sub>) done on previously cleared devices to give the user the added capability as well as a better value.

### DESCRIPTION

The Hewlett-Packard HP M2600A OmniCare Telemetry System consists of a pocket sized digital synthesized transmitter, synthesized receiver, and a mainframe that accommodates up to eight receiver channels. Patient physiological parameter information is displayed on HP M2350A/60A, a central station device.

Patient physiological parameter displays, controls, recordings and alarms are controlled from an HP M2350A/60A Component Central Monitor. Recordings can also be initiated from the transmitter. System functions such as bedside overview, remote arrhythmia monitoring, remote data management and remote clinical data access are available to the user at the central station. No changes were made to the ST or arrhythmia monitoring algorithms.

The addition of SpO<sub>2</sub> monitoring is a new feature compared to the HP telemetry predicate device and is the most significant change.

Two changes were made to ECG monitoring. A third lead was added and pace pulse detection is now done in software as opposed to hardware with similar performance.

The new system utilizes synthesized tuning as opposed crystal module replacement to select a new channel. An infra-red serial port was added to the transmitter for communication with an external service tool to facility tuning.

The new system leverages heavily off of Hewlett-Packard devices previously cleared. The system is a digital UHF system that uses the same antenna devices, and much of the same transmitter and receiver design as the predicate device. The SpO<sub>2</sub> capability is based on existing cleared devices. The HP M1020A SpO<sub>2</sub> electronics were modified to work in the transmitter. New patient studies for SpO<sub>2</sub> were done as part of the validation work for the new system.

### INTENDED USE

The device is intended to provide ambulatory and nonambulatory monitoring of ECG and SpO<sub>2</sub> parameters of adult, and pediatric patients in a professional health care facility. It is intended to be used by trained health care personnel. It is not intended for home use.

### SUBSTANTIAL EQUIVALENCE

HP M2600A OmniCare Telemetry System is a replacement for the present telemetry system. The device was compared to predicate devices to show equivalence with respect to safety, intended use, and efficacy. The comparison shows the device to be substantially equivalent in safety, effectiveness, and intended use to legally marketed devices. The discussion of similarities and differences shows that there are no significant differences between the modified device and the predicate devices.